IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TEXARKANA DIVISION

[UNDER SEAL], on behalf of the UNITED STATES OF AMERICA, *et al.*, **Plaintiffs/Relator,** **v.** **[UNDER SEAL],** **Defendants.**	**Civil Action No.** **COMPLAINT AND JURY DEMAND** **Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)**

FILED UNDER SEAL

HEALTH CHOICE GROUP, LLC, on behalf of the UNITED STATES OF AMERICA; STATE OF ARKANSAS; STATE OF CALIFORNIA; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; DISTRICT OF COLUMBIA; STATE OF FLORIDA; STATE OF GEORGIA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF MARYLAND; COMMONWEALTH OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MINNESOTA; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH CAROLINA; STATE OF OKLAHOMA; STATE OF RHODE ISLAND; STATE OF TENNESSEE; STATE OF TEXAS; STATE OF VERMONT; COMMONWEALTH OF VIRGINIA; and STATE OF WASHINGTON,

Plaintiffs/Relator,

v.

BAYER CORPORATION; AMGEN INC.; ONYX PHARMACEUTICALS, INC.; AMERISOURCEBERGEN CORPORATION; and LASH GROUP,

Defendants.

Civil Action No.

COMPLAINT AND JURY DEMAND

Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)

The United States of America (the "United States") and the Plaintiff States (the United States and Plaintiff States are collectively referred to herein as the "Government"), by and through their *qui tam* Relator Health Choice Group, LLC (the "Relator"), allege:

PRELIMINARY STATEMENT

1. This is a civil action brought on behalf of the Government under the Federal False Claims Act, 31 U.S.C. § 3729 – 3733 (the "False Claims Act" or "FCA") and the false claims acts of the respective Plaintiff States[1] to recover treble damages sustained by and civil penalties

[1] The state statues are the: (1) Arkansas Medicaid Fraud False Claims Act, Ark. Code Ann. §§ 20-77-901 – 911 (as amended by 2017 Arkansas Laws Act 978 (S.B. 564)); (2) California False Claims Act, Cal. Gov't Code §§ 12650 – 12656; (3) Colorado Medicaid False Claims Act, Colo. Rev. Stat. Ann. §§ 25.5-4-303.5 – 4-310; (4) Connecticut False Claims and Other Prohibited Acts Under State-Administered Health or Human Services Programs Act, Conn. Gen. Stat. Ann. §§ 4-274 – 289; (5) Delaware False Claims and Reporting Act, Del. C. Ann. tit. 6, §§ 1201 – 1211; (6) District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act of 2012, D.C. Code Ann. §§ 2-381.01 – 381.10; (7) Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 – 68.092; (8) Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 – 4-168.6; (9) Hawaii False Claims to the State Act, Haw. Rev. Stat. Ann. §§ 661-21 – 31; (10) Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. §§ 175/1 – 175/8; (11) Indiana False Claims and Whistleblower Protection Act, Ind. Code Ann. §§ 5-11-5.5-1 – 5.5-18; (12) Iowa False Claims Act, Iowa Code Ann. §§ 685.1 – 685.7; (13) Louisiana Medical Assistance Programs Integrity Law, La. Stat. Ann. §§ 437.1 – 440.16; (14) Maryland False Claims Act, Md. Code Ann. Health-Gen. §§ 8-101 – 111; (15) Massachusetts False Claims Law, Mass. Gen. Laws Ann. ch. 12, §§ 5A – 5O; (16) Michigan Medicaid False Claim Act, Mich. Comp. Laws Ann. §§ 400.601 – 400.615; (17) Minnesota False Claims Act, Minn. Stat. Ann. §§ 15C.01 – 15C.16; (18) Montana False Claims Act, Mont. Code. Ann. §§ 17-8-401 – 416; (19) Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. §§ 357.010 – 357.250; (20) New Hampshire Medicaid Fraud and False Claims Act, N.H. Rev. Stat. Ann. §§ 167:61-b – 61-e; (21) New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 – 32C-18; (22) New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 – 14-15; (23) New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 – 9-14; (24) New York False Claims Act, N.Y. Fin. Law §§ 187 – 194; (25) North Carolina False Claims Act, N.C. Gen. Stat. Ann. §§ 1-605 – 618; (26) Oklahoma Medicaid False Claims Act, Okl. Stat. Ann. tit. 63, §§ 5053 – 5054; (27) Rhode Island State False Claims Act, R.I. Gen. Laws Ann. §§ 9-1.1-1 –1.1- 9; (28) Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 – 108; (29) Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 – 185; (30) Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 – 36.132; (31) Vermont False Claims Act, Vt. Stat. Ann. tit. 32, §§ 630 – 642; (32) Virginia Fraud Against Tax Payers Act, Va. Code Ann. §§ 8.01-

and restitution owed to the Government as a result of a multi-tiered kickback scheme involving defendants Bayer Corporation ("Bayer"), Amgen, Inc. and its subsidiary Onyx Pharmaceuticals, Inc. (Amgen and Onyx collectively referred to as "Amgen"), AmerisourceBergen Corporation ("Amerisource"), and Lash Group ("Lash"), all collectively referred to herein as "Defendants."

2. Defendants' unlawful conduct involves (1) Betaseron, a Bayer product approved for the treatment of multiple sclerosis ("MS"); and (2) Nexavar, a product co-marketed by Bayer, Amgen, and Onyx and approved for the treatment of cancer. Collectively, Betaseron and Nexavar are referred to herein as the "Covered Products."

3. To enrich themselves at the expense of the Government, Bayer and Amgen, with substantial assistance from Amerisource and Lash, engaged in three intertwined, unlawful marketing schemes for the Covered Products.

4. First, with assistance from Lash and Amerisource, Bayer and Amgen provided in-kind remuneration to Prescribers[2] in the form of free nursing services to induce them to prescribe the Covered Products to their patients.

5. Second, Bayer and Amgen contracted with and paid remuneration to Amerisource and Lash to deploy nurse educators to recommend Betaseron and Nexavar to Prescribers and patients. While purporting to provide independent medical advice and disease-awareness information, the nurse educators were in reality acting as undercover sales reps for Bayer and Amgen, focused on the singular mission they were paid to accomplish: refer the Covered Products to Prescribers and patients.

216.1 – 216.19; and (33) Washington Medicaid Fraud False Claims Act, Wash. Rev. Code Ann. §§ 74.66.005 – 74.66.130.

[2] As used herein, the term "Prescriber" refers to any physician or Advance Practice Provider authorized to write prescriptions, as well as their employers.

6. Third, with assistance from Lash, Bayer and Amgen provided in-kind remuneration to Prescribers in the form of reimbursement support services, saving Prescribers thousands of dollars in administrative expenses. These reimbursement support services were provided to induce Prescribers to prescribe the Covered Products to their patients.

7. The federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (the "AKS"), expressly prohibits any individual or entity from offering, paying, soliciting, or receiving any "remuneration," which includes "any kickback, bribe, or rebate," to "any person to induce such person" to purchase or recommend a drug or service that is covered by Medicare or Medicaid. *Id.* Further, the U.S. Department of Health and Human Services (the "HHS") has repeatedly warned pharmaceutical companies that they should refrain from engaging in marketing or promotional activities that rely on individuals involved in the delivery of healthcare or on the provision of free services such as billing, nursing, or other staff services. *See, e.g.*, 56 Fed. Reg. 35952-01, 35981 (July 29, 1991); 59 Fed. Reg. 65372-01, 65376 (Dec. 19, 1994).

8. Although Bayer and Amgen, as well as their co-defendants, knew that the AKS prohibited them from giving kickbacks to promote the Covered Products, Defendants disregarded the law, choosing instead to put sales growth and profits before their duties to comply with the law and ensure patient safety and integrity in the healthcare marketplace. Tens of thousands of patients were prescribed the Covered Products not based on clinical efficacy or patient-specific information, but rather as a result of the unlawful, substantial kickbacks Bayer and Amgen offered Prescribers.

9. Based on Defendants' illegal marketing and promotion schemes, pharmacies have submitted and continue to submit claims to Medicare and Medicaid that were tainted by kickbacks, causing these programs to pay billions of dollars in improper reimbursements.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the Government's claims pursuant to 28 U.S.C. §§ 1331 and 1345.

11. This Court may exercise personal jurisdiction over Bayer, Amgen, Onyx, Amerisource, and Lash because a substantial part of the acts giving rise to the Government's claims occurred within the State of Texas.

12. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1391(c) because Bayer, Amgen, Onyx, Amerisource, and Lash each transact business in this District and/or, in furtherance of its fraudulent kickback schemes, caused to be submitted or conspired to submit false claims in this District.

THE PARTIES

13. Bayer is an American subsidiary of Bayer AG, a German multinational chemical and pharmaceutical company headquartered in Leverkusen, Germany. Bayer is the world's sixteenth largest pharmaceutical company with estimated revenues of $15.5 billion in 2014.[3]

14. Amgen is an American multinational biopharmaceutical corporation headquartered in Thousand Oaks, California. According to its website, Amgen is the world's largest independent biotechnology firm.

15. Onyx is a biopharmaceutical company headquartered in San Francisco, CA. Onyx is a subsidiary of Amgen. According to a Press Release on Amgen's website, Onyx has at

[3] *Top 25 Pharma Companies*, PMLive, http://www.pmlive.com/top_pharma_list/global_revenues, (last visited June 15, 2017).

least two partnered oncology assets with Bayer, one of which is Nexavar, a Covered Product.[4]

16. Amerisource is a corporation headquartered in Chesterbrook, PA. According to its website, Amerisource provides services from product commercialization and distribution to pharmacy, provider, and manufacturer solutions. In 2015, Amerisource's revenue was $135 billion.[5]

14. Lash is a healthcare consulting firm headquartered in Fort Mill, South Carolina. According to its website, Lash offers both clinical nurse educator services as well as reimbursement support services. Lash is a subsidiary of Amerisource. A case study on Lash's website boasts about its nurse educator services: "Lash Group's nurse educators opened doors to areas that are typically not open to drug manufacturers' sales representatives, such as hospitals and clinics."[6] In fact, the case study is named "Nurse Educators Helped Boost New Product Adoption."

15. Relator Health Choice Group, LLC is an affiliate of the National Healthcare Analysis Group ("NHAG"), a research organization based in New Jersey. Each year, NHAG representatives conduct hundreds of interviews of participants in the healthcare marketplace – nurses, sales reps, office managers, administrators, reimbursement support personnel, etc. – to form an understanding of industry practices.

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[4] Amgen Press Release, *Amgen to Acquire Onyx Pharmaceuticals for $25 Per Share in Cash* (Aug. 25, 2013), http://investors.amgen.com/phoenix.zhtml?c=61656&p=irol-newsArticle&ID=1849611 (last visited June 17, 2017).

[5] Amerisourcebergen Corp., Annual Report (Form 10-K) at 24 (Nov. 24, 2015), https://www.sec.gov/Archives/edgar/data/1140859/000104746915008939/a2226704z10-k.htm (last visited June 15, 2017).

[6] *Case Study: How Nurse Educators Helped Boost New Product Adoption*, Lash Group, at 2 (Summer 2011), http://www.lashgroup.com/resources/dyn/files/730239zb175c895/_fn (last visited June 15, 2017).

16. Relator brings this action on behalf of the Government pursuant to the *qui tam* provisions of the federal False Claims Act, 31 U.S.C. § 3729 – 3733 and the false claims acts of the respective Plaintiff States.

STATUTORY BACKGROUND

17. In relevant part, the FCA, 31 U.S.C. § 3729(a)(1)(A) – (C), establishes treble damages liability to the United States for any individual or entity that:

> knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; or
>
> knowingly makes or uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or
>
> conspires to commit a violation of [the foregoing paragraphs].

Within the meaning of the FCA, "knowingly" is defined to include reckless disregard and deliberate ignorance. 31 U.S.C. § 3729(b)(1). In addition to treble damages, the FCA also provides for assessment of a civil penalty for each violation or each false claim.

18. In relevant part, the AKS, 42 U.S.C. § 1320a-7b, provides as follows:

> (b) Illegal Remunerations.
>
> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> > (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> >
> > (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

19. For purposes of the AKS, "remuneration" includes the transfer of anything of value, whether cash or in-kind consideration, directly or indirectly, covertly or overtly. Importantly, the statute has been interpreted to cover any arrangement where one purpose of the remuneration is to obtain money for referral of services or to induce further referrals.

20. The AKS is designed to, among other things, ensure that patient care will not be improperly influenced by inappropriate compensation from the pharmaceutical industry, and that healthcare professionals remain free of conflicts of interest that could impact treatment decisions.

21. To ensure compliance, every federally-funded health care program requires every provider or supplier to ensure compliance with the provisions of the AKS and other federal laws governing the provision of health care services in the United States.

22. The AKS was amended in March 2010 as part of the Patient Protection and Affordable Care Act ("PPACA"), which clarified that all claims resulting from a violation of the AKS constitute violations of the FCA. 42 U.S.C. § 1320a-7b(g). The PPACA also makes clear that violations of its anti-kickback provisions, like violations of the FCA, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." Pub. L.

No. 111-148, 124 STAT. 759 § 6402 (adding new section, § 1128J(h)).

23. Knowingly providing kickbacks to Prescribers to induce them to prescribe a drug (or to influence prescriptions) to individuals who seek reimbursement for the drug from a federal Government healthcare program or causing others to do so, while certifying compliance with the AKS (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates the FCA.

24. A violation of the AKS constitutes a felony. Any party convicted under the AKS must be excluded from federal health care programs for a term of at least five years. 42 U.S.C. § 1320a-7(a).

25. Compliance with the AKS is required for reimbursement of claims from federal health care programs, and claims made in violation of the law are actionable civilly under the FCA. 42 U.S.C. § 1320a-7b(g) (stating, in part, that "a claim that includes items or services resulting from a violation of . . . [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]"); *see also United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 313 (3d Cir. 2011) (stating that "[c]ompliance with the AKS is clearly a condition of payment under Parts C and D of Medicare").

26. The AKS contains statutory exceptions and certain regulatory "safe harbors" that exclude certain types of conduct from the reach of the statute. *See* 42 U.S.C. § 1320a-7b(b)(3). None of the statutory exceptions or regulatory safe harbors protect Defendants from liability for the conduct alleged herein.

27. Each of the Plaintiff States has enacted statutes that are parallel to the legislative scheme embodied in the FCA and the AKS.

AFFECTED HEALTH PROGRAMS

28. Generally, when a Prescriber prescribes one of the Covered Products, a patient is provided with a prescription that is then filled at a pharmacy. The pharmacy then submits the claim for payment to the relevant federal health care program(s) for reimbursement.

29. In certain circumstances, a federal program may also have pharmacy facilities that directly dispense prescription drugs. In such cases, the federal health care program purchases the drug directly rather than reimbursing the pharmacy.

Medicare

30. Medicare is a federal program that provides federally-subsidized health insurance primarily for persons who are 65 or older or are disabled. *See* 42 U.S.C. §§ 1395 *et seq.* ("Medicare Program").

31. Part D of the Medicare Program was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, to provide prescription drug benefits for Medicare beneficiaries. Medicare Part D became effective January 1, 2006.

32. All persons enrolled in Medicare Part A or Medicare Part B are eligible to enroll in a prescription drug plan under Part D. HHS, through its component agency, the Center for Medicare and Medicaid Services ("CMS"), contracts with private companies (or "Part D sponsors") to administer prescription drug plans. Such companies are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D sponsors enter into subcontracts with many pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

33. Generally, after a Prescriber writes a prescription for a patient who is a Medicare

beneficiary, that patient can take the prescription to a pharmacy to be filled. When the pharmacy dispenses drugs to the Medicare beneficiary, the pharmacy submits a claim electronically to the beneficiary's Part D sponsor (sometimes through the sponsor's pharmacy benefit manager, or "PBM"). The pharmacy receives reimbursement from the sponsor (or PBM) for the portion of the drug cost not paid by the beneficiary. The Part D sponsor is then required to submit to the CMS an electronic notification of the drug dispensing event, called the Prescription Drug Event ("PDE"), which contains data regarding the prescription claim, including the service provider of the drug, the prescriber of the drug, the quantity dispensed, the amount paid to the pharmacy, and whether the drug is covered under the Medicare Part D benefit.

34. Payments to a Part D Plan sponsor are "conditioned upon the provision of information to CMS that is necessary" for CMS to administer the Part D program and make payments to the Part D Plan sponsor for qualified drug coverage. 42 C.F.R. § 423.322. CMS's instructions for the submission of Part D prescription PDE claims data state that "information . . . necessary to carry out this subpart" includes the data elements of a PDE. PDE records are an integral part of the process that enables CMS to administer the Part D benefit. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program.

35. CMS gives each Part D sponsor advance monthly payments consisting of the Part D sponsor's plan's direct subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor), estimated reinsurance subsidies for catastrophic coverage, and estimated low income subsidies. 42 C.F.R. §§ 423.315, 423.329. At the end of the payment year, CMS reconciles the advance payments paid to each Part D sponsor with the actual costs the sponsor

has incurred. In this reconciliation process, CMS uses the PDE claims data it has received from the Part D sponsor during the prior payment year to calculate the costs the Part D sponsor has actually incurred for prescriptions filled by Medicare beneficiaries under Part D. If CMS underpaid the sponsor for low-income subsidies or reinsurance costs, it will make up the difference. If CMS overpaid the sponsor for low-income subsidies or reinsurance costs, it will recoup the overpayment from the sponsor. After CMS reconciles a plan's low-income subsidy and reinsurance costs, it then determines risk-sharing amounts owed by the plan to CMS or by CMS to the plan related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs exceeded or fell below a target amount for the plan by certain threshold percentages. 42 C.F.R. § 423.336.

36. CMS's payments to the Part D sponsor come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R. § 423.315(a).

37. To receive Part D funds from CMS, Part D Plan sponsors, as well as their authorized agents, employees, and contractors (including pharmacies), are required to comply with all applicable federal laws, regulations, and CMS instructions.

38. By statute, all contracts between a Part D Plan sponsor and the HHS must include a provision whereby the Plan sponsor agrees to comply with the applicable requirements and standards of the Part D program as well as the terms and conditions of payment governing the Part D program. 42 U.S.C. § 1395w-112(b)(1).

39. Medicare Part D Plan sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse, including the FCA and AKS. 42 C.F.R. § 423.505(h)(l).

40. In accordance with these express statutory and regulatory requirements, all contracts entered into between CMS and Plan D Plan sponsors from 2006 through the present include a provision in which the sponsor "agrees to comply with . . . Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. §§ 3729 *et seq.*), and the Anti-Kickback Statute (section 1128B(b) of the Act)." 42 C.F.R. § 423.505(h)(1).

41. CMS regulations further require that all subcontracts between Part D Plan sponsors and downstream entities (such as pharmacies and PBMs) contain language obligating the entities in question to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv).

42. A Part D Plan sponsor also is required to certify to the accuracy, completeness and truthfulness of the PDE claims data submitted to CMS. Specifically, the relevant regulatory provision, entitled "Certification of data that determine payment," provides in relevant part:

> (1) General rule. As a condition for receiving a monthly payment under subpart G of this part (or for fallback entities, payment under subpart Q of this part), the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.
>
> (2) Certification of enrollment and payment information. The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

> (3) Certification of claims data. The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) (or for fallback entities, under § 423.871(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement.

42 C.F.R. § 423.505(k).

43. Compliance with the regulatory requirement that the PDE data submitted to CMS be true, accurate, and complete is a condition of payment under the Medicare Part D program. *See id.* at 423.505(k)(1).

44. In accordance with this regulatory requirement, since the Part D program began, Medicare required each Part D Plan sponsor to sign annually an Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor ("Attestation"). This Attestation states:

> Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and the Medicare Part D Organization(s) listed above, hereafter referred to as the Part D Organization, governing the operation of the contract numbers listed above, the Part D Organization hereby makes the following attestations concerning CMS payments to the Part D Organization:
>
> The Part D Organization attests that based on its best knowledge, information, and belief, the final Prescription Drug Event (PDE) data that have been submitted to and accepted by CMS as of [date] with respect to the Part D plans offered under the above-stated contract(s) for the dates of service of January 1, [prior year] to December 31, [prior year], are accurate, complete, and truthful and reflect all retroactive adjustments of which the Part D organization has been informed by May 30, [current year]. In addition, the Part D Organization attests that based on best knowledge, information, and belief, the payments that have been made by the Part D organization for the claims summarized by the aforementioned PDE data were made in accordance with the coordination of benefits guidance in Chapter 14 of the Medicare Prescription Drug Benefit Manual and other applicable CMS guidance. The Part D Organization attests that based on its best knowledge, information, and belief as of the date(s) of last successful DIR [Direct and Indirect Remuneration Data] [prior year] data submission(s) via the Health Plan Management System (HPMS) as listed above, the final direct and indirect remuneration data submitted to

> CMS for the Part D plans offered under the above-stated contract(s) for the [prior] coverage year are accurate, complete, and truthful and fully conform to the requirements in the Medicare Part D program regulations and the Final Medicare Part D DIR Reporting Requirements for [the prior year]. The Part D Organization also certifies that based on its best knowledge, information, and belief as of the date indicated below, all other required information provided to CMS to support the determination of allowable reinsurance and risk corridor costs for the Part D plans offered under the above-stated contract(s) is accurate, complete, and truthful. With regards to the information described in the above paragraphs, the Part D Organization attests that it has required all entities, contractors, or subcontractors, which have generated or submitted said information (PDE and DIR data) on the Part D Organization's behalf, to certify that this information is accurate, complete, and truthful based on its best knowledge, information, and belief. In addition, the Part D Organization attests that it will maintain records and documentation supporting said information. The Part D Organization acknowledges that the information described in the above paragraphs will be used for the purposes of obtaining federal reimbursement and that misrepresentations or omissions in information provided to CMS may result in Federal civil action and/or criminal prosecution.

45. All approved Part D Plan sponsors who received payment under Medicare Part D in benefit years 2006 through the present date submitted these required Attestations in the same or similar format.

46. Medicare regulations further provide: "If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement." 42 C.F.R. § 423.505(k)(3).

47. Medicare also enters into agreements with physicians to establish the physician's eligibility to participate in the Medicare program. To be eligible for participation in the Medicare program, physicians must certify that they agree to comply with the Anti-Kickback Statute, among other federal health care laws. Specifically, on the Medicare enrollment form,

CMS Form 855I, the "Certification Statement" that the medical provider signs states: "You MUST sign and date the certification statement below in order to be enrolled in the Medicare program. In doing so, you are attesting to meeting and maintaining the Medicare requirements stated below." Those requirements include:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me . . . . The Medicare laws, regulations and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

Medicaid

48. Medicaid is a joint federal-state program created in 1965 that provides health care benefits for certain groups, primarily the poor and disabled. Each state administers a State Medicaid program.

49. The federal Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A). While drug coverage is an optional benefit, the Medicaid programs of all states provide reimbursement for prescription drugs.

50. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Federal funding under Medicaid is provided only when there is a corresponding state expenditure for a covered Medicaid service to a Medicaid recipient. The federal government pays to the state the statutorily established share of the "total

amount expended . . . as medical assistance under the State plan." 42 U.S.C. § 1396b(a)(l).

51. The vast majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies generate funding requests to the state Medicaid programs.

52. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding each state will be permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims, including claims from pharmacies seeking payment for drugs, are presented for payment. After the end of each quarter, the state submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). 42 C.F.R. § 430.30.

53. Claims arising from illegal kickbacks are not authorized to be paid under state regulatory regimes. In fact, providers who participate in the Medicaid program must sign enrollment agreements with their states that certify compliance with the state and federal Medicaid requirements, including the AKS. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished.

54. Furthermore, in many states, Medicaid providers, including both physicians and pharmacies, must affirmatively certify compliance with applicable federal and state laws and regulations.

55. For example, in New York, physicians and pharmacies must periodically sign a

"Certification Statement for Provider Billing Medicaid," in which the provider certifies that claims submitted "to the State's Medicaid fiscal agent, for services or supplies furnished, [. . .] will be subject to the following certification . . . . I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations."

TRICARE

56. TRICARE is part of the United States military's health care system, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel, and military retirees and their dependents. The military health system, which is administered by the Department of Defense ("DOD"), is composed of the direct care system, consisting of military hospitals and military clinics, and the benefit program, known as TRICARE. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations, and fee-for-service benefits.

57. TRICARE prescription drug benefits are provided through three different programs: military treatment facility outpatient pharmacies, TRICARE network retail pharmacies, and TRICARE's mail order service. TRICARE contracts with a PBM to administer its retail and mail order pharmacy programs. In addition, TRICARE beneficiaries can also pay out-of-pocket to fill prescriptions at non-network retail pharmacies, and submit a claim for reimbursement directly with TRICARE's PBM. The claims process is different for each of these pharmaceutical programs.

58. When a TRICARE beneficiary brings a prescription to a TRICARE network retail

pharmacy, for example, the pharmacy submits an electronic claim to the PBM for that prescription event. The PBM sends an electronic response to the pharmacy that confirms the beneficiary's TRICARE coverage, and, if the prescription claim is granted, informs the pharmacy of the calculated pharmacy reimbursement amount and the co-pay (if applicable) to be collected from the beneficiary. The pharmacy then collects the co-pay amount (if any) from the beneficiary and dispenses the medication. After a 10-day hold to ensure the prescription was picked up and not returned to the shelf by the pharmacy, the PBM sends a TRICARE Encounter Data ("TED") record electronically to TRICARE. The TED record includes information regarding the prescription event, including the reimbursement amount to be paid to the dispensing pharmacy. TRICARE then authorizes the PBM to make payment to the pharmacy for the amount remaining (after co-pay) on the claim. The PBM sends the payment to the pharmacy. After the payment is made by the PBM's bank, the PBM's bank requests reimbursement from the Federal Reserve Bank ("FRB"). The FRB then transfers funds to the PBM's bank account.

59. If the prescription is filled at a non-network retail pharmacy, the beneficiary must pay the full price of the prescription to the pharmacist and file a claim for reimbursement on DD Form 2642, TRICARE/DOD.CHAMPUS Medical Claim- Patient's Request for Medical Payment ("Form 2642"). The Form 2642 is mailed to the PBM. As in the case of reimbursements under the retail pharmacy program, a TED record is created and sent to TRICARE. TRICARE then authorizes payment to the TRICARE beneficiary. Upon receiving that authorization, the PBM issues a check to the beneficiary, which is drawn on the PBM's bank account. TRICARE then reimburses the PBM in the same manner as it does under the retail pharmacy program, such that funds are transferred from the FRB to the PBM's bank account.

60. TRICARE beneficiaries can also fill prescriptions through TRICARE's mail order

pharmacy program. TRICARE beneficiaries submit prescriptions by mail, fax, or electronically to TRICARE's PBM, along with any co-pay (if applicable). TRICARE's PBM delivers the prescription to the beneficiary via free standard shipping. The medications dispensed through the mail order pharmacy program are filled from the PBM's existing inventory of pharmaceuticals. The PBM then requests replenishment pharmaceuticals from DOD's national prime vendor contracted by the Defense Logistics Agency ("DLA"). DOD procures the pharmaceuticals through its national prime vendor and replenishes the PBM's inventory of pharmaceuticals. The PBM then submits a TED record to TRICARE to obtain administrative fees. DLA bills TRICARE directly for drug replenishment costs.

61. Pursuant to 38 U.S.C. § 8126, pharmaceutical manufacturers are required to enter into national contracts with the DOD pursuant to which the manufacturer makes available for procurement certain covered drugs at the Federal Ceiling Price (a price that is calculated as at least 24% less than the manufacturer's average price based on all sales to commercial customers through a wholesaler or distributor). Pursuant to DOD's contract with its national prime vendor, the national prime vendor submits an invoice to the DOD for payment of pharmaceuticals supplied to the PBM in connection with the mail order pharmacy program, charging the DOD the price set by the contract awarded by the DOD to the drug manufacturer.

62. Since March 2003, TRICARE has contracted with a pharmacy benefits manager, Express Scripts, Inc. ("ESI"), to administer TRICARE's mail order pharmacy programs. ESI has also administered TRICARE's retail pharmacy program since June 2004.

63. Similarly, TRICARE's military treatment facilities purchase medications through procurement contracts with third party pharmaceutical prime vendors. When a TRICARE beneficiary submits an outpatient prescription to a military treatment facility's outpatient

pharmacy, the pharmacy purchases the medication from the prime vendor pursuant to an existing procurement contract, and the drug is then dispensed to the patient.

64. While some physicians enroll in the TRICARE program as network or participating providers, any physician that is licensed, accredited and meets other standards of the medical community is authorized to provide services to TRICARE beneficiaries. Physicians who are enrolled in the TRICARE network must expressly certify their compliance with TRICARE's regulations. Yet all providers that provide services to TRICARE beneficiaries, whether network providers or non-participating providers, are required to comply with TRICARE's program requirements, including its anti-abuse provisions. 32 C.F.R. § 199.9(a)(4). TRICARE regulations provide that claims submitted in violation of TRICARE's anti-abuse provisions can be denied. *Id.* § 199.9(b). Kickback arrangements are included within the definition of abusive situations that constitute program fraud. *Id.* § 199.9(c)(12).

Veterans Administration Health Care

65. The Department of Veteran Affairs ("VA") maintains a system of medical facilities from which all pharmaceutical supplies, including prescription drugs, are procured directly by the VA. A VA beneficiary can take a prescription to a VA medical facility, at which point the VA dispenses the medication to the VA beneficiary from its existing inventory. The VA also supports a mail service prescription program as part of its outpatient drug benefit. VA beneficiaries can submit prescriptions to that mail service program, and the VA then dispenses pharmaceuticals purchased by the VA directly to VA beneficiaries. The VA medical system serves approximately four million veterans.

66. The VA purchases the pharmaceuticals that it dispenses at its medical facilities and through its mail service prescription program through its Federal Supply Schedule ("FSS")

program. Pursuant to Public Law 102-585, pharmaceutical manufacturers are required to enter into national contracts with the VA pursuant to which the manufacturer makes available for procurement certain covered drugs at the Federal Ceiling Price. A VA facility that requires a supply of a particular medication (including a mail order facility) submits a purchase order to the VA's pharmaceutical prime vendor for distribution of pharmaceuticals.

67. Pursuant to the PPACA, among other things, all claims to Government reimbursed programs resulting from a violation of the AKS are also a violation of the FCA.

68. Moreover, the statutes and regulations set forth above concerning Medicare, Medicaid, TRICARE, and Veterans Administration Health Care, when viewed together, state that healthcare providers must comply with the AKS in order for claims they cause to be submitted to these programs to be reimbursed.

69. Here, the claims submitted for the Covered Products violated the AKS because they stemmed from prescriptions that were tainted by kickbacks, while the participants in the scheme knew that claims for reimbursement would be submitted to the above programs. As such, and as more fully discussed below, the prescribing healthcare providers expressly and impliedly falsely certified compliance with the conditions of payment for, at least, Medicare, Medicaid, TRICARE, and Veterans Administration Health Care.

70. In addition to falsely certifying compliance with the AKS, the healthcare providers also falsely certified compliance with contractual provisions that were conditions for payment.

RELATOR'S INVESTIGATION

71. To unmask Defendants' unlawful conduct, Relator and its representatives interviewed numerous individuals with knowledge of the scheme.

- Confidential Interviewee #1 ("CI-1") was employed by Lash as a nurse educator for Betaseron from 2007 until March of 2014. Her territory was southeast Virginia, central and eastern North Carolina, and northeast South Carolina.
- Confidential Interviewee #2 ("CI-2") was employed by Amerisource as a nurse educator for Betaseron from 2002 until October of 2015. Her territory included the State of Minnesota.
- Confidential Interviewee #3 ("CI-3") was a drug rep for Bayer from December 2012 until July of 2014. Her territory was Buffalo, New York and the surrounding area.
- Confidential Interviewee #4 ("CI-4"), was employed by Lash as a reimbursement support services representative for Betaseron from October 2012 until March of 2015. Her territory included the northeast part of the United States.
- Confidential Interviewee #5 ("CI-5") was employed by Lash as a nurse educator for Nexavar from 2013 until 2015. Her territory was the State of New Jersey.
- Confidential Interviewee #6 ("CI-6") was employed by Bayer as a Nexavar drug rep from 2005 until 2013. His territory was the State of Illinois.
- Confidential Interviewee #7 ("CI-7") was employed by Lash as a reimbursement support services representative from September 2013 until February 2014. Her territory included various parts of the United States.

THE FRAUDULENT SCHEMES

72. Based on Relator's investigation, there is overwhelming evidence that Bayer and Amgen, with substantial assistance from Amerisource and Lash engaged in a complex, multi-part scheme that involved the payment of kickbacks to Prescribers for the purpose of increasing

prescriptions for the Covered Products.

73. In the first scheme, with assistance from Amerisource and Lash, Bayer and Amgen provided free nurse services to Prescribers to induce them to recommend the Covered Products to their patients..

74. In the second scheme Bayer and Amgen contracted with and paid remuneration to Amerisource and Lash to deploy nurse educators to recommend the Covered Products to Prescribers and patients, thereby blurring the lines between independent medical advice and sales.

75. In the third scheme, with assistance from Lash, Bayer and Amgen provided in-kind remuneration in the form of reimbursement support services, saving Prescribers thousands of dollars in administrative expenses, to induce Prescribers to recommend the Covered Products.

Scheme One: Free Nurse Services

76. In its first scheme, Bayer and Amgen offered free nurse education and patient management services to induce Prescribers to recommend the Covered Products over competitor products. Bayer and Amgen provided these services through Amerisource and Lash nurses.

77. Most Prescribers typically allocate between 10 to 15 minutes to see routine patients. However, patients suffering from MS and cancer often require extra office time, training, and resources to manage their disease. For this purpose, to treat MS and cancer patients, Prescribers frequently rely on certified nurse educators. The cost associated with the use of nurse educators, however, is significant – a nurse educator often commands an annual salary that exceeds $60,000, or an average hourly wage of $40.00 per hour.

78. Seeking to exploit the needs of Prescribers and healthcare organizations and the challenges they face in managing patients affected by chronic diseases, Bayer and Amgen

developed a marketing strategy that involved furnishing nurse educators to Prescribers to induce them to prescribe the Covered Products. As CI-2 explained, "When it was discovered that patients needed so much more than what they were getting, a golden opportunity appeared."

79. Bayer's MS nurse educator program is called "Beta Plus" (as in "Betaseron"), and the nurse educators are referred to as "Beta Nurses." Bayer and Amgen's nurse educator program for Nexavar is called "Nex Connect" and the nurse educators are sometimes referred to as "Clinical Support Specialists." Beta Plus has been around for at least the last decade and had roughly 120 nurse educators at its peak. The Beta Plus program ended in 2015. The Nexavar nurse educator program began at least as far back as 2009. According to CI-5, a Nexavar nurse educator, Beta Nurses were simply moved from the Beta Plus program to Nex Connect when the Beta program ended. The Nexavar program includes roughly 28 nurse educators. Both of these programs were/are available to patients across the United States.

80. Bayer and Amgen's nurse educator patient trainings were one-on-one sessions between a nurse educator and a Prescriber's patient. The trainings were usually in the patient's home and the length of the training varied between 40 minutes and an hour and a half. Patients could receive in-person training multiple times, depending on the patient's needs. Patients received telephonic follow-ups from nurse educators at scheduled intervals; for example, at two weeks, one month, two months, etc. In general, Betaseron patients received one in-person training from a nurse educator, while Nexavar patients were trained in-person twice.

81. Patient training sessions included training regarding disease state, answering patient questions, assisting with insurance coverage, and teaching on how to administer the Covered Products.

82. Prescribers were encouraged to enroll all patients using the Covered Products into

these patient support programs so that the nurse educators could begin to directly manage these patients and free the Prescriber from the time and expense of doing so.

83. Bayer and Amgen drug reps and nurse educators were trained to encourage Prescribers to off-load their patients to the nurse educators for management. CI-1, a Beta Nurse, explained:

> [W]hen we [nurse educators] come in, of course we try to convince [Prescribers] that we are well-trained in Betaseron and even though their nurses are very capable, this is something that we do on a daily basis and we talk about every part of our [patient] training. In most cases they'll go, "Well, we [Prescribers] don't have the time to be able to do that for our patients." And a lot of times they'll talk to the sales people that *they're prescribing specifically to get a Beta nurse in the house*.

84. CI-2, also a Beta Nurse, offered her nurse educator services by saying "consider me being the eyes and ears of your clinic, but in [the patient's] home. So I can give you [Prescribers] information and feedback and observations that you can't make because you only see them when they come in and they only share as much as they want to share with you. When I meet with them, in their homes, I get more information, even if it's just by observation." CI-2 further explained that she persuaded Prescribers by saying, "Give me one patient. Let me prove to you that I can make a difference, and if that works, if that made a difference, then we'll go from there."

85. CI-5, a Nexavar nurse educator, explained how she approached Prescribers:

> The general oncology practice, . . . [is] extremely busy. They see hundreds of patients a day . . . [so] very often one of the complaints that patients had, which is what a lot of providers would come and tell me is that, the nurses and staff did not have sufficient amount of time to spend with the patient, explaining the titration of dosing, side effects, what to do if this happens, what to do if that happens. So, one of the ways that I approached the practitioners to utilize those services was: "I understand you have these newly diagnosed patients that you wish you could spend hours with getting them comfortable and moving them through this process," and . . . they don't have that. So that's where I can come in, I am a

> trained oncology nurse and I can then go to the patient's home where they're comfortable, and their family around me, and spend as much time as that patient need[s]. Then they will have direct access to me after that.

86. The nurse educator programs provide a valuable, tangible, benefit to Prescribers. CI-1, a Beta Nurse, stated that her role was "like another nurse for the doctor . . . we were part of the team, where doctors could call us and we could call the doctors." She explained that her role was very interactive with the Prescriber; nurse educators and Prescribers would collaborate when treating patients.

87. CI-2, another Beta Nurse explained the benefit to Prescribers in the following way:

> Well, going back to that "give me one patient. Let me prove to you that I can make a difference," . . . [Prescribers] gave [nurse educators] their most difficult patient. The one that's always calling them. The one that always has questions about side effects. The one that wants to come in and be seen all the time. If you can get that patient and help manage that patient, it saves [Prescribers] from getting phone calls from the patient, returning phone calls for that patient, guiding the patient on how to manage their side effects, or needing to come in excessively. So it saves office time. It saves them consequently then, money because they're not spending time reassuring and reiterating the message that they've already told this patient who just is needy and either isn't remembering it or just has excessive needs. You help manage those patients so that the office doesn't have to.

88. Both CI-1 and CI-2 also explained that part of their role was to help patients overcome "needle phobia," as Betaseron is a self-injectable medication. Further, CI-3, an MS drug rep, also believed that the Betaseron nurse educator services were a tangible benefit to Prescribers. The benefit to Prescribers can also be seen by the sheer number of Prescribers who utilized or are utilizing nurse educator services. CI-3 estimated that 95% of Prescribers who prescribed Betaseron also utilized the nurse educator services.

89. CI-5, a Nexavar nurse educator, explained the benefit to Prescribers by noting that:

> [T]here were a couple of offices that had such a great number of patients that usually . . . would do the initial training very quickly right there in the office at the time of the visit. And then, if that patient needed additional training, . . . [Prescribers] just kept a list and at the end of the week they would send me the list and say, "[Y]ou may want to just touch base with each of them [patients]." . . . [T]hat would save [Prescribers] time and money . . . . They would tell the patient, "You're going to get a call from the Nexavar nurse. She is going to make sure you're feeling okay and go over everything. If you needed this training or help or follow up, this is her number you can call her."

CI-5 further stated that "when [Prescribers are] familiar with the fact that [Bayer and Amgen] have this great nursing service that will walk the patients and hold their hands through the process, where they can . . . write the script [and] take a step back . . . instead of [dealing with] the patient calling continuously with questions of confusion, that's a big positive for many offices."

90. CI-6, a Nexavar drug rep, "agree[d]" that nurse educator services were a tangible benefit to Prescribers. In particular, he stated:

> [Nurse educators] [k]eep the patients in the loop completely. Sometimes in offices, the physician [ ] has other patients, of course, and there is not a real close relationship outside of the regular appointment. But the patient sometimes needs someone that they feel a little bit more comfortable talking to as far as side effects [and] how to take [the Covered Products]. Those discussions are really important to staying on therapy. So I think the nurse educator plays a really big role as far as helping the nurse give the information to the patient and that's the most important thing [–] to really make sure that the patient is comfortable taking a particular pharmaceutical product.

CI-6 also estimated that 60% of Prescribers who prescribed Nexavar utilized the nurse educator services.

91. In sum, in return for prescribing the Covered Products to patients, Prescribers reduced the time and cost required to treat those patients, freed up time to see other patients, and increased profitability. The nurse educators are effectively free employees given to Prescribers in exchange for the Prescribers' commitment to recommend the Covered Products over

competing products. Bayer and Amgen, with the assistance of Lash and Amerisource, enabled Prescribers to "eliminate an expense that [they] would have otherwise incurred"[7] if they directly employed the nurse educators or provided the services themselves. Bayer and Amgen's "Free Nurse" marketing scheme thus violates the AKS.

Scheme Two: White Coat Marketing by Nurse Educators

92. Since at least 2006, with assistance from Amerisource and Lash, Bayer and Amgen have relied on nurse educators to help promote the Covered Products, obtain better access to Prescribers, and influence Prescribers to prescribe the Covered Products.

93. Prescribers often restrict or deny access to drug reps, but tend to be more willing to meet with healthcare professionals. Accordingly, Bayer and Amgen resorted to nurse educators to gain access to Prescribers and promote the Covered Products.

94. Bayer and Amgen's relationship with Amerisource and Lash plainly involves the payment of kickbacks – cash consideration – in return for services that led to prescriptions being filled and paid for with Government money.

95. In this case, Bayer and Amgen paid remuneration to nurse educators to recommend the Covered Products over competing products to Prescribers and patients. The nurses were likely to be viewed by Prescribers as better credentialed and more credible than traditional drug reps, and, thus, they were more likely to gain access to Prescribers and their staff.

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[7] *OIG* Compliance Program Guidance for Pharmaceutical Manufacturers, Dep't of Health & Human Servs., 68 Fed. Reg. 23731-01, 23737 (May 5, 2003), https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf (if "services provided by the manufacturer eliminate an expense that the physician would have otherwise incurred (*i.e.*, have independent value to the physician) . . . the arrangement may be problematic if the arrangement is tied directly or indirectly to the generation of federal health care program business for the manufacturer").

96. The Office of Inspector General ("OIG") refers to the practice of utilizing healthcare providers, like nurses, to promote particular drugs as "white coat marketing," and has warned against the practice.

> The fraud and abuse risks are compounded where . . . a physician or other health care professional is involved in the marketing activity—a practice sometimes referred to as "white coat" marketing. White coat marketing is closely scrutinized under the anti-kickback statute because physicians and other health care professionals are in an exceptional position of public trust and thus may exert undue influence when recommending health care-related items or services . . . .[8]

97. Bayer and Amgen paid Amerisource and Lash to hire nurse educators to recommend the Covered Products to Prescribers and patients and drive sales.

98. Bayer, Amgen, Amerisource, and Lash needed a clever approach to disguise this marketing strategy. After all, the nurses could not openly play the role of drug reps for at least three reasons. First, Prescribers would potentially limit nurse access, in the same manner that drug rep access was being limited. Second, if Prescribers knew that the nurses were nothing more than sales reps in disguise, Prescribers would discount the nurses' "recommendations" as biased. Third, the OIG has identified white coat marketing as particularly suspect and the AKS prohibits pharmaceutical companies from paying non-employees to "recommend" its drugs to others.[9] Since the nurses involved in this scheme were not Bayer or Amgen employees, Bayer, Amgen, Amerisource, and Lash could not openly pay the nurses to exclusively recommend the Covered Products.

99. In an attempt to circumvent the law, Bayer and Amgen contrived a disease awareness program that would act as a cover for the nurses, seemingly distinguishing them from

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[8] *See, e.g.*, OIG Op. 11-08, at 6 (Jun. 14, 2011), https://oig.hhs.gov/fraud/docs/advisoryopinions/2011/AdvOpn11-08.pdf.

[9] 42 U.S.C. § 1320a-7b(b).

drug reps and enabling them to appear to be independent. Bayer, Amgen, Amerisource, and Lash designated the nurses as "educators" who, instead of being paid to recommend drugs, were purportedly there to promote free educational services to Prescribers.

100. Although the nurses were independent contractors and were purportedly "educators," they were expected to and did recommend the Covered Products. This conclusion is compelled by numerous facts Relator uncovered during its investigation.

101. ***Bayer and Amgen provided sales training to the nurse educators***. Bayer and Amgen invested heavily in training nurse educators how to gain access to Prescribers and promote the Covered Products. This training was a *vital* component of Bayer and Amgen's scheme because Bayer and Amgen's ultimate goal was to drive drug sales.

102. CI-1 explained that she was trained on what to say to Prescribers because "we were able to actually make visits without the sales [rep] and that's why it was more important for us to know the correct things to say." CI-1 would often report back to the Prescriber after a patient's training, so she was taught how to use that interaction to promote Betaseron. She noted that she "could not compare other medications, but we could talk about all the benefits and the things that we saw that the patients were able to benefit from the drug [Betaseron]." Further, CI-1 explained that she was trained on how to deal with doctors who are "really anti-Betaseron or injections." Similarly, CI-2, a Beta Nurse, indicated that she was trained on how to overcome Prescriber and staff objections.

103. Another way that nurse educators were trained was through role-playing exercises. For example, CI-5, a Nexavar nurse educator, stated that the role-plays "with health care providers it was more or less, ensuring that their patients were receiving the best care and [learning] what services should be provided [by the nurse educator]." She noted that when she

was going to visit Prescribers with the drug reps, the drug rep "would take on the selling . . . all of the PI information, statistics, indication, and I would come in with the clinical side effects, patients, training, and everything else that went along with that."

104. ***The nurse educators were actively used by Bayer and Amgen to drive sales.*** Once trained, Bayer and Amgen selectively deployed nurse educators to target Prescribers and facilities with high potential to prescribe the Covered Products. To maximize the chances of success, the nurse educators coordinated with Bayer and Amgen drug reps and would often accompany the drug reps on sales calls.

105. CI-1, a Beta Nurse, stated that the drug rep and herself "usually plan a month ahead on the different offices we're going to go visit." The drug rep "would actually meet with me and say, 'We're going to see these particular doctors.'" CI-1 indicated that they decided which doctors to visit by "basically target[ing] the higher prescribing ones. Just because we wanted to continue to stay on top of them and because we were seeing so many of their patients." CI-1 further stated: "I'd look at my database to see what patient I'd recently trained or did follow up calls with and we [drug rep and nurse educator] would prep before we went to see each doctor."

106. CI-2, a Beta Nurse, explained that she would target providers based on the number of referrals she got: "clearly, if you've got one clinic who's giving you five referrals a week, they're an important case and they're an important provider and they're going to be somebody you want to have a lot of communication with and pay attention to." CI-2 indicated that targeting was also "based on a history of what [the Prescriber's] referral pattern was already and a history of need. For instance, some clinics had their own educators in the clinic . . . [a]nd some didn't. And you would know what that was. You would know which clinics were a no-see

clinic . . . ."

107. ***Nurse educators gained access to Prescribers.*** Once trained, nurse educators immediately began to gain access and infiltrate Prescriber offices and facilities. For example, CI-1, a Beta Nurse, explained "It was such a big plus for the sales rep to be able to travel with a Beta nurse. So, they wanted us out there as soon as possible to meet any new doctors . . . ." She further indicated that she

> would go to a lot of conferences or meetings and if I bumped into a doctor in my territory that I never met, I would basically go up and introduce myself . . . . I would say, "I travel with my rep in D.C. and we haven't been able to actually visit your office. When can we actually set up an appointment to come in as a team?" And oftentimes they'll say, "Oh! Check in with my staff." They'd give you a specific name and somehow we'd get an in and say, "My nurse met your doctor and he said to go ahead and set up an appointment."

108. Given their training, education, and experience, nurse educators were able to gain access to potential Prescribers in some circumstances where drug reps could not. CI-2, a Beta Nurse, said, "Even though we'd go to clinics together [with a drug rep], we would then separate off and I would speak to healthcare providers separately . . . ."

109. CI-3, a Betaseron drug rep, explained how nurse educators' post-patient training reports to the Prescriber helped gain access "because the nurse educators may have information that is specific to a patient . . . . so then you could discuss more specifics related to [the Prescriber's patients]."

110. In CI-5's experience, "very often now . . . doctor's offices have posted right on their doors 'we will not see drug reps' . . . . [S]o often, I can get my foot in the door . . . . I've worked with many of the nurses in my area . . . and the doctors and sometimes it's just [that the Prescribers] like dealing with another health care practitioner instead of somebody that they feel [is] trying to sell them something . . . ."

111. CI-6, a Nexavar drug rep, agreed. "It's getting more difficult now to get in to the oncology offices primarily because of the Sunshine Act . . . depending on the individual practice. So any time you can have access from a nursing point of view that really helps you with . . . promoting your product in that particular practice."

112. ***The nurse educators were tasked with promoting Bayer and Amgen Covered Products.*** The real mission of the nurse educators was to increase prescriptions of Bayer and Amgen Covered Products.

113. The nurse educators generally did not discuss competitors. CI-1, a Beta Nurse, stated, "we aren't allowed to talk about competitor drugs." CI-2, a Beta Nurse, explained that, "It's not that you can't say the other company's names, drugs, therapies, whatever, but you can't discuss it at all." CI-5, a Nexavar nurse educator, also explained that she was not allowed to discuss other treatment options: "[W]e're only allowed to talk about our particular drug. We don't really get into other therapies."

114. This situation highlights the promotional aspect of the nurses' "education." A true nurse educator's role would inherently include a discussion of the many treatment options for MS or cancer. However, these nurse educators focused on the benefits of the Covered Products.

115. CI-1, a Beta Nurse, explained how she focused on patient experiences during post-patient training reports to the Prescriber when promoting Betaseron.

> [T]he pharmaceutical rep, they only can talk about the drug itself . . . . [T]hey're not able to talk first-hand . . . . We [nurse educators] just have such a different relationship with the physicians. So, when we're talking about the data or we're talking about patient experiences, for some reason, they seem to listen to our story a little bit differently because we're actually speaking first hand as to what our patients [on Betaseron] are experiencing or how the disease has developed with

> certain patients . . . . [I]t's like we have a different message because we're bringing specific patient information.

116. CI-2, a Beta Nurse, explained how she promoted her services and the Covered Products: "You were there to help educate. To get them [Prescribers] to understand why, using you as an educator and consequently then, *that product* [Betaseron], was now going to be helpful for the patient."

117. CI-5, a Nexavar nurse educator, "strongly agree[d]" that a nurse educator working for a pharmaceutical company will promote that company's drug as the medication of choice. She said "If I sign on to support the drug, I've done my research and I truly feel that it's beneficial so I have no problem supporting that drug and only that drug in comparison to the others that [are] on the market."

118. CI-6, a Nexavar drug rep, similarly explained how nurse educators help promote Nexavar.

> [Nurse educators] definitely have a part as far as educating, especially [educating] the nurse practitioners because the nurse practitioners can actually prescribe and they have a lot of influence with the oncologists. So by having the [nurse educators] come in and talk about Nexavar and side-effect management, [this] gives [nurse practitioners] a bit more education about Nexavar and increase[s] the comfort level as far as recommending it for a particular patient.

119. ***The nurse educators engaged in direct marketing to patients.*** Amerisource and Lash nurse educators also promoted the Covered Products directly to MS and cancer patients. As with the Prescribers, by purporting to educate patients, white coated nurse educators would be in a prime position to recommend and promote the Covered Products directly to these patients.

120. Importantly, these encounters were direct nurse-to-patient contacts that, in general, took place at lunch or dinner programs and health fairs. These patient education sessions could be used to actively convert patients from their current medications to the Covered

Products.

121. CI-2, a Beta Nurse, explained her experience, stating:

> That was our strong suit [–] educating patients about our treatment option . . . . [W]e didn't cover others, just our own. We frequently saw patients who were, what we called, therapy-naïve, meaning they haven't been on any of the medication[s], or who had been on multiple medications and felt sometimes there was re-learning to be done or trying to get rid of information from the past that maybe wasn't as clear or effective for them. That was one of our strongest points in our whole position . . . . We would do things like, meet at health fairs, at the booths. Then people would come by and want to ask questions and they'd do comparisons between your treatment option and someone else's treatment option and sometimes the difference was just in how educated you were on the information. Sometimes that alone was what helped them make their decision.

122. CI-1, a Beta Nurse, explained that programs occurred about once per month. She gave an example of the type of messaging that took place at these functions and said, "we spent a lot of time talking about the easy-to-use, steel-reinforced injectors . . . ." CI-1, did not, however, discuss Betaseron. Yet, the patients "knew that we were representing Beta Nurses and the Betaseron product . . . . [and] [t]here was usually a table that had a lot of the brochures." There were, however, program speakers, usually a Betaseron prescribing nurse practitioner, who would present information that contained comparison data for the different medications. And, while the presentation didn't explicitly say that Betaseron was superior, the data clearly showed it. In CI-1's opinion, the presentations were such that "you could see clearly the information that they're trying to get across to the audience."

123. CI-5, a Nexavar nurse educator, explained that, just like the Beta Nurses did for MS patients, she would also educate cancer patients who may be on another oncology medication. She explained that the programs occurred every one to two months. She stated that sometimes patients would ask her to compare their current drug to Nexavar. CI-5 stated that this

was a "tricky" situation because she "couldn't get too much into a direct comparison." She would simply go over the side-effects and profile of Nexavar and tell the patients what they could expect. However, as stated previously, CI-5 had no issue promoting Nexavar.

124. In sum, Bayer and Amgen's nurse educator programs were nothing more than a scheme to drive prescriptions for the Covered Products. By compensating nurses to recommend the Covered Products, the Defendants violated the AKS.

Scheme Three: Reimbursement Support Services

125. To induce recommendations of the Covered Products over competing products, Bayer and Amgen, with the assistance of Lash, offered a third type of kickback: free reimbursement support services for Prescribers who wrote prescriptions for the Covered Products.

126. This remuneration was a tangible in-kind benefit that greatly reduced, and in some instances eliminated, Prescribers' administrative costs related to prescribing the Covered Products.

127. Through Lash, Bayer and Amgen hired and trained dozens of skilled workers to provide free reimbursement support services, including patient insurance benefit verification services, patient prior authorization services, and coverage appeals (collectively "Support Services").

128. Lash highlighted its Support Services on its website:

> Our dedicated site coordinators strive to become an *extension of the provider's team*, with a single point-of-contact case management approach that streamlines and optimizes reimbursement processes.[10]

[10] Lash Reimbursement, http://www.lashgroup.com/services/reimbursement, (last visited June 15, 2017).

129. Bayer and Amgen's drug reps and Lash's reimbursement support services representatives marketed the Support Services when detailing the Covered Products to increase the likelihood that Prescribers would prescribe the Covered Products. Put simply, in exchange for prescribing the Covered Products, Bayer and Amgen would assume the Prescribers' administrative responsibilities and costs associated with starting a patient on the Covered Products. The more a Prescriber prescribed the Covered Products as a percentage of its overall prescription volume, the greater the savings and profits to the practice, as time and money spent on Support Services would now be handled by Bayer and Amgen. As detailed below, the Bayer and Amgen Support Services were the "carrot" (remuneration) dangled to induce Prescribers to prescribe the Covered Products to their patients.

130. ***Support Services are a tangible benefit to Prescribers***. Support Services have a great value to Prescribers because these services reduce, and in some instances eliminate, the administrative costs associated with prescribing drugs. These services also help increase profitability, particularly for office-based Prescribers, who derive most of their revenue from billing 15, 30, and 45-minute units of service provided to patients during office visits.

131. The technical term for an office visit is "evaluation and management services" or "E/M." In 2012, the most commonly billed Medicare physician service was the $70 "doctor office visit" for a 15-minute consultation, closely followed by the $100 "doctor office visit" for a 30-minute consultation. Medicare pays over $11 billion each year for E/M services alone. Medicaid and private insurers also pay billions each year.

132. When an office-based Prescriber receives payment for an E/M service, the payment is intended to compensate the Prescriber for medical care given *and* administrative tasks associated with that patient's care. These tasks include conducting a patient's prescription drug

insurance benefit verification, determining if the drug is on the formulary lists and tiers, seeking a coverage determination, determining co-pays and deductibles, conducting telephone calls to patients, responding to patient complaints, returning messages and faxes, handling prescription refill requests, and, where necessary, obtaining prior authorizations[11] and managing the resulting paper trail.[12] Despite these enormous administrative costs and expenses,[13] office-based Prescribers are not permitted to directly charge patients a fee for any of these services. Instead, Prescribers get paid for these services indirectly through the E/M unit charge.

133. Since a Prescriber's E/M reimbursement for each office visit is fixed per unit, Prescribers are continuously seeking ways to combat overhead costs and reduce expenses in order to earn more profit from each E/M unit billed.

134. One way to earn more profit is by reducing the administrative costs associated

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[11] A study of 12 primary care practices published in the Journal of the American Board of Family Medicine put the mean annual projected cost per full-time equivalent physician for prior authorization activities between $2,161 and $3,430. The study's authors concluded that "preauthorization is a measurable burden on physician and staff time." *See* Christopher P. Morley, et al., *The Impact of Prior Authorization Requirements on Primary Care Physicians' Offices: Report of Two Parallel Network Studies*, 26 J. Am. Bd. Fam. Med. 93-95 (Jan.-Feb. 2013).

[12] In 2006, primary care providers spent a mean of 1.1 hours per week on authorizations, primary care nursing staffs spent 13.1 hours, and primary care clerical staff spent 5.6 hours, according to a 2009 study published in Health Affairs. The study estimated that the overall cost to the healthcare system of all practice interactions with health plans, including authorizations, was between $23 billion and $31 billion annually. *See* Lawrence P. Casalino, et. al., *What Does it Cost Physician Practices to Interact with Health Insurance Plans?* 28 Health Affairs 533-543 (May 14, 2009), http://content.healthaffairs.org/content/28/4/w533.full.

[13] A 2011 study published in Health Affairs found that providers spend an annual average of nearly $83,000 of overhead staff time and costs associated with coverage plan issues. With approximately 835,000 physicians practicing in the nation, this translates to over $69 billion annually. *See* Dante Morra, et. al., *US Physician Practices Versus Canadian; Spending Nearly Four Times as Much Money Interacting with Payers*, 30 Health Affairs 1443-1450 (Aug. 3, 2011) http://content.healthaffairs.org/content/30/8/1443.full.pdf+html.

with prescribing drugs. If a Prescriber can reduce this cost, each E/M unit will be more profitable. These economics have a direct impact on a Prescriber's prescribing behavior. Prescribers are less likely to prescribe a drug that imposes an undue burden on support staff because doing so would mean a decrease in profitability resulting from the need to hire more staff or reduce the number of patients that can be seen in a day. Conversely, a Prescriber is much more likely to prescribe a drug if it can be prescribed with little or no administrative burden. Thus, the Prescriber's relative cost and burden in prescribing one company's drug when compared to another company's drug can directly influence which drug a Prescriber will recommend to a patient.

135. These factors are not lost on pharmaceutical manufacturers like Bayer and Amgen. Indeed, Bayer and Amgen readily incurred the expense of providing Support Services knowing that these services would act as a powerful inducement to Prescribers to recommend the Covered Products over a competitor's products.

136. While pitching Prescribers, Bayer and Amgen sales reps emphasized that, if the Prescribers prescribed the Covered Products, Bayer and Amgen would provide the services and resources of a full reimbursement support team to manage the administrative tasks associated with prescribing the drug. Bayer and Amgen sales reps further emphasized that the cost and expenses normally associated with managing a patient's prescription would be shifted to Bayer and Amgen, thereby increasing the Prescriber's bottom line.

137. This value proposition was a powerful tool in the hands of the Bayer and Amgen drug representatives, and it was used to induce Prescribers to recommend the Covered Products. CI-6 specifically noted that his message to Prescribers included noting that his company was there to "make it easy for their reimbursement services within the [Prescriber's] office."

138. Because many drugs are expensive, most, if not all patients, cannot afford therapy unless it is covered by insurance. As a result, successfully starting patients on a drug therapy typically requires an initial determination to verify whether the patient has adequate prescription drug coverage. This process is called "benefit verification." For most Prescribers, the verification of a patient is performed by staff and it is a time-consuming task. It can take multiple calls and over an hour just to determine the nature and extent of the patient's coverage. However, if the Prescriber recommends the Covered Products, the verification task for the Covered Products is handled by Lash's staff, rather than the Prescriber's staff.

139. Each day, Lash's office receives requests from Prescribers to perform benefit verifications for patients. Each request is immediately forwarded to a verification specialist. The specialist verifies the source of the patient's primary and secondary insurance benefits (*i.e.*, private insurance, Medicare, TRICARE, and/or Medicaid), and contacts that insurer to verify the nature and extent of the patient's drug benefit coverage. In cases of Medicare and Medicaid, this is called a "coverage determination." For Medicare patients, coverage determinations tend to be particularly cumbersome and time-consuming given the complexity of many Part D plans.[14]

140. In addition to verifications and coverage determinations, Bayer and Amgen also provide prior authorization services. Many insurance carriers require a Prescriber to obtain a prior authorization before prescribing certain medications. Further, if a medication receives an authorization, that authorization may only be valid for a limited time, such as for one year or a

[14] These plans generally have four coverage phases: (1) the deductible phase, where patients pay 100% for drug costs until the deductible amount; (2) the initial coverage limit phase, where patients pay a percentage of the cost depending on the carrier and the drug's formulary position; (3) the coverage gap or "donut hole" phase, where, in 2015, patients paid 45% of the cost for brand-name drugs and 65% of the cost for generic drugs; and (4) the catastrophic coverage phase, where, in 2015, patients paid either 5% of the covered drug cost or $2.65 for generics and $6.60 for brand name drugs.

month. After that, the Prescriber must start the prior authorization process over again. The most expensive Covered Products almost always require prior authorizations from a patient's drug coverage plan, and, therefore, these services are particularly valuable to Prescribers. In fact, the cumbersome process often causes Prescribers to choose less expensive medications that do not require a prior authorization. Indeed, the Part D carriers use the prior authorization process as a means to contain costs associated with expensive drugs. Thus, if a Prescriber wants to recommend more expensive drugs, the Part D carriers require the Prescriber to go through the administrative process and make the case for prescribing the drug over a less expensive option. However, Bayer and Amgen have relieved Prescribers of that burden in order to induce them to prescribe the Covered Products over competing medications.

141. Bayer and Amgen also provide a service to appeal authorization and coverage denials. If a patient's carrier denies coverage for the Covered Products or denies the prior authorization request, Bayer and Amgen take steps to reverse the adverse determination.

142. The process of obtaining a prior authorization and/or appealing a denial requires direct input from the Prescriber regarding the patient's medical history, clinical and laboratory findings, and other information to establish the patient's medical necessity for a particular drug. The Prescriber and his or her staff must also develop specialized knowledge about each carrier's unique prior authorization and coverage criteria. Although these steps ordinarily require substantial time and expertise from the Prescriber and their staff, Prescribers are not permitted to charge a fee separate from the E/M unit charge. Bayer and Amgen arranged for personnel to handle prior authorizations and appeals, giving a clear advantage *and* tangible financial incentive to Prescribers who choose to prescribe the Covered Products over competitors.

143. Bayer and Amgen Support Services are widely used by Prescribers who prescribe

the Covered Products. CI-3, a Betaseron drug rep, estimated that 95% of the Prescribers who prescribed Betaseron utilized Lash's Support Services. CI-6, a Nexavar drug rep, estimated that 70% of the Prescribers who prescribed Nexavar utilized the Support Services.

144. CI-4, a reimbursement support services representative for Betaseron, believes that offering reimbursement support has a positive net impact in terms of prescriptions and refills because, "It helps [Prescribers] not have to worry too much about if that patient can actually have that medication because you have specialists behind you who [are] contacting the insurance company."

145. Further, CI-6, a Nexavar drug rep, explained that he would go so far as to bring a reimbursement manager into Prescribers' offices to train staff and help with Support Services. He said, "So what I did as far as explaining it to the offices, [is] I brought in a reimbursement manager. And we had an in-service with physicians and also with the person in the [Prescriber's] office that does the reimbursement . . . . I brought in a REACH[15] coordinator to talk to the reimbursement person [in the Prescriber's office] and that was a . . . closer relationship because we were talking about individual patients for delivery times, making sure that everything on the money side runs pretty smoothly."

146. The Support Services have real value to Prescribers. Without them, Prescribers would have to use their own staff and resources or outsource the Support Services to a private vendor. Bayer and Amgen give Prescribers a means to "outsource" this function without any direct or indirect cost to the Prescriber, but *only if* the Prescriber prescribers the Covered Products.

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[15] The reimbursement support program for Nexavar is called REACH.

147. ***Violations of Medicare regulations regarding patient privacy and duty of care.*** Relator's investigation also revealed that while carrying out these Support Services, Lash violated Medicare regulations regarding patient privacy and duty of care. CI-4, a Lash reimbursement support services representative for Betaseron, explained that when she performs these services and contacts a patient's insurance benefit drug plan representative, she has been trained to identify herself as calling from "patient coordination" or "patient assistance program." Similarly, CI-7, a Lash reimbursement support services representative for Nexavar, explained that when she would call a patient's insurance benefit drug plan representative, she used to identify herself as "calling from the doctor's office." CI-7 admits that after some complaints, her script was changed to say, "calling on behalf of the doctor's office."

148. These statements are a misrepresentation of Lash's role, as they are neither a patient's "appointed representative" nor "calling from the doctor's office," and circumvent Medicare privacy rules regarding the coverage determination and appeal process.

149. Medicare rules give patients the right to prompt coverage determinations and the right to seek a reconsideration of an adverse coverage determination. These rights are afforded to all patients seeking prescription coverage for drugs, including MS and cancer patients who have been prescribed Covered Products. As is detailed above, the coverage determination requires contacting the patient's Part D carrier and/or Medicaid carrier and conveying medical information about the patient and the patient's particular need for the medication. Because of privacy and HIPAA concerns, Medicare rules only permit three parties to seek a coverage determination: 1) the patient; 2) the prescribing physician; and 3) the patient's appointed representative. 42 CFR 423.560. Lash is neither the patient nor the prescribing physician. Further, Lash is also not the patient's "appointed representative."

150. Medicare regulations define "appointed representative" as follows:

> Appointed representative means an individual either appointed by an enrollee or authorized under State or other applicable law to act on behalf of the enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process. Unless otherwise stated in this subpart, the appointed representative has all of the rights and responsibilities of an enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M of this chapter.

42 C.F.R. 423.560.

151. There are typically stringent State rules regarding the form and manner in which this appointment can be made.

152. Neither Bayer, nor Amgen, nor Lash appear to follow these rules; therefore none of them can claim to be the patient's representative. Thus, since Lash is not the patient, the prescribing physician, nor the patient's appointed representative, it lacks the legal authority to engage in the Support Services offered to induce Prescribers to recommend the Covered Products.[16] Such conduct raises significant privacy and patient care concerns.

DEFENDANTS' ILLEGAL CONDUCT GIVES RISE TO A DISTURBING CONFLICT OF INTEREST

153. Defendants' conduct creates a disturbing conflict of interest for the Prescribers

[16] Bayer may assert that it is acting as the appointed agent of the prescribing physician. This purported agency is not authorized by the Medicare regulation nor would Medicare likely authorized such an arrangement. A physician seeking a coverage determination on behalf of a patient will likely be in the patient's Part D carrier's network and under a contract with the Part D carrier. This contract necessarily imposes obligations upon the physician to act truthfully, honestly and ethically in each and every interaction with the Part D carrier. These contracts also undoubtedly have penalties and consequences if these obligations are not met by the Prescriber/pharmacy. Finally, these contracts and the physician's own duty of care impose a duty to act in the best interest of the patients. In seeking Betaseron and/or Nexavar reimbursement, Lash has none of these obligations and duties, and unlike the physician, has a direct financial self-interest in obtaining coverage for Betaseron and/or Nexavar.

and nurse educators involved therein. This conflict can harm patients and vastly increase pharmaceutical spending.

154. Medical professionals are expected to have no allegiance to or affiliation with any drug or drug company. Rather, medical professionals are duty-bound to make treatment decisions based solely upon the best interests of their patients. During recent years, scholars have raised concerns that increased promotional spending by pharmaceutical companies on nurses (mostly in the form of small gifts, dinners or drug samples) is creating a serious conflict, and have suggested that a ban or strong limitation on such conduct is needed to protect patients.[17]

155. The conflict created by Bayer and Amgen's conduct, which extends far beyond simple gifts and drug samples, is significant. By using nurse educators to promote, and creating incentives for Prescribers to prescribe, the Covered Products, Bayer and Amgen have created a conflict with the Prescribers' duty of care to patients. The Prescribers and nurses may consciously or subconsciously recommend the Covered Products despite cheaper alternatives or more effective treatments, to the detriment of a patient and the Government.[18]

156. The conflict of interest manifests in two related situations, continuity of care[19] and medication adherence. A Prescriber's decision to keep a patient on a certain drug or switch to a

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[17] Nancy J. Crigger, *Pharmaceutical Promotions and Conflict of Interest in Nurse Practitioner's Decision Making: The Undiscovered Country*, 17 J. Am. Academy of Nurse Practitioners 207-12 (May 27, 2005).

[18] Judith A. Erlen, *Conflict of Interest – Nurses at Risk!*, 27 Orthopaedic Nursing 135-39 (Mar. – Apr. 2008). Erlen argues that a nurse simply accepting small gifts (such as notepads and promotional items) or listening to a marketing pitch is enough to cloud their judgment and create a conflict of interest. *Id.* at 137. This is a far cry from the situation highlighted here where the nurse *is indirectly employed* by the drug manufacturer.

[19] Continuity of care is concerned with quality of care over time. It is the process by which the patient and his/her physician-led care team are cooperatively involved in ongoing health care management toward the shared goal of high quality, cost-effective medical care.

competing drug should be based on patient outcomes. Bayer and Amgen's conduct, however, aligns the interest of the Prescribers and nurse educators with that of the drug company, to the detriment of the patients.

157. As CI-1, a Beta Nurse, explained, "We [ ] could not compare other medications, but we could talk about all the benefits and the things that we saw that the patients were able to benefit from the drug [Betaseron]." CI-2, a Beta Nurse similarly stated:

> In my position, we did not talk about all treatment options because it was competition and there's not a good way to do that. It's difficult. You don't want to talk about your competition and say things that are bad or good . . . . Acknowledge that you have competition and that yes, all of these drugs work. Different drugs will work for different patients. You need to narrow the focus in talking about your own particular drug instead of selling other people's medicine.

Similarly, CI-5, a Nexavar nurse educator, explained "we're only allowed to talk about our particular drug. We don't really get into other therapies." She also noted that, "If I sign on to support the drug, I've done my research and I truly feel that it's beneficial. So I have no problem supporting that drug and *only* that drug in comparison to the others that are on the market."

158. Nurse educators' inherent conflict of interest also manifests in situations regarding medication adherence. CI-2, a Beta Nurse, explained that she was exposed to statistics regarding nurse educators and medication adherence. She said "we had all kinds of glossy figures and marketing information about percentages of adherence on this medication before we used these [nurse educator] services. Here's the percentage of adherence and compliance after we implement these services. [T]hey were always dramatic. We could get a 20% increase in adherence and compliance just by instituting a nurse educator . . . ."

159. CI-5, a Nexavar nurse educator, agreed. Discussing the benefit to pharmaceutical companies of deploying nurse educators, she said:

> I think the overall benefit is being able to track the prescription and maintain [medication] compliance . . . . In a way it's the pharmaceutical company's benefit too – keeping a finger on the pulse of how people are doing once that script is written. Because we both know doctors can write names of a prescription [drug], but if nobody's selling [the drug] or staying compliant with [the drug], that's going to cut into [the pharmaceutical company's] economic upside.

160. Medication adherence benefits Bayer and Amgen by increasing prescription refills. Yet, in the course of caring for patients, there may be times when a patient would have a better outcome by switching to a more effective drug or a less expensive drug. Indeed, a Prescriber's decision to keep a patient on a certain drug or switch to a competing drug should be driven solely by patient outcomes. However, since these nurse educators and Prescribers' interests are aligned with Bayer and Amgen's interest, their independence is compromised. Defendant's conduct not only violates the AKS, but raises ethical and patient safety issues for the nursing profession.

THE BREADTH OF BAYER AND AMGEN'S KICKBACK SCHEME

161. The evidence uncovered during Relator's investigation reveals a kickback scheme of truly breathtaking proportions.

162. The scheme encompasses every Prescriber that, since at least 2006, received, directly or indirectly, "free nurse" services that were paid for by Bayer or Amgen.

163. The scheme encompasses every Prescriber that, since 2006, received a visit from a nurse educator that purported to provide "education" concerning MS and cancer on behalf of Bayer and Amgen.

164. The scheme encompasses every Prescriber that, since at least 2006, received Support Services that were paid for by Bayer and Amgen.

165. Bayer, Amgen, and their co-Defendants profited from the illegal schemes described in this Complaint, and Medicare, Medicaid, TRICARE, and Veteran Administration

Healthcare were made to bear the costs.

166. Since at least 2006, Defendants' actions knowingly have caused pharmacies, PBMs, Part D sponsors, fiscal intermediaries and others to submit millions of dollars in claims to Government programs for Covered Products provided to beneficiaries as a result of Defendants' illegal marketing and quid pro quo arrangements. Those false claims have caused the Government to disburse billions of dollars in reimbursements that were tainted by kickbacks and should not have been paid.

COUNT 1 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE FALSE CLAIMS ACT: PRESENTING FALSE CLAIMS FOR PAYMENT (31 U.S.C. § 3729(a)(1)(A))

167. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

168. Relator seeks relief against Defendants under Section 3729(a)(1)(A) of the FCA, 31 U.S.C. § 3729(a)(1)(A).

169. As a result of Bayer and Amgen offering or paying, and Bayer and Amgen's co-Defendants, physicians, and other health care professionals soliciting or receiving, kickbacks to purchase, order, or recommend the purchasing or ordering of Covered Products in violation of the federal AKS, 42 U.S.C. § 1320a-7b(b)(1) and (b)(2), Defendants caused false and fraudulent claims for payment to be presented to federal health care programs.

170. Accordingly, Defendants knowingly caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

171. By reason of the false or fraudulent claims that Defendants knowingly caused to be presented to federal health care programs, the United States has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary

penalty for each false claim.

COUNT 2 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE FALSE CLAIMS ACT: USE OF FALSE STATEMENTS (31 U.S.C. § 3729(a)(1)(B))

172. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

173. Relator seeks relief against Defendants under Section 3729(a)(1)(B) of the FCA, 31 U.S.C. § 3729(a)(1)(B).

174. As a result of Bayer and Amgen offering or paying, and Bayer and Amgen's co-Defendants, physicians, and other health care professionals soliciting or receiving, kickbacks to purchase, order, or recommend purchasing or ordering Covered Products in violation of the federal AKS, 42 U.S.C. § 1320a-7b(b)(1) and (b)(2), Defendants knowingly caused pharmacies, PBMs, Part D sponsors, fiscal intermediaries, and others to make false records or statements that were material to getting false or fraudulent claims paid by federal health care programs.

175. More specifically, the pharmacies, PBMs, Part D sponsors, fiscal intermediaries, and others, falsely certified, and/or represented that the reimbursements they sought for Covered Products were in full compliance with applicable federal and state laws prohibiting fraudulent and false reporting, including but not limited to the AKS. Those false certifications, statements, or representations caused federal health care programs to pay out sums that would not have been paid if those programs had been made aware of the falsity of the certifications, statements, or representations.

176. Accordingly, Defendants caused the use of false records or statements material to false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(B).

177. By reason of these false records or statements, the United States has been

damaged in a substantial amount to be determined at trial, and is entitled to treble damages plus a monetary civil penalty for each false record or statement.

COUNT 3 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE FALSE CLAIMS ACT: CONSPIRING TO VIOLATE THE FALSE CLAIMS ACT (31 U.S.C. § 3729(a)(1)(C))

178. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

179. Relator seeks relief against Defendants under Section 3729(a)(1)(C) of the FCA, 31 U.S.C. § 3729(a)(1)(C).

180. As set forth above, Bayer and Amgen conspired with Amerisource and Lash, physicians, and other health care professionals to offer or pay kickbacks in exchange for, or to induce them to purchase, order, or recommend the purchasing or ordering of Covered Products in violation of the federal AKS, 42 U.S.C. § 1320a-7b(b)(1) and (b)(2), thereby causing false and fraudulent claims to be presented to federal health care programs seeking reimbursement for Covered Products dispensed in connection with the kickback scheme.

181. Accordingly, Defendants conspired to commit violations of 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), in violation of 31 U.S.C. § 3729(a)(1)(C).

182. By reason of the Defendants conspiracy to violate 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), the United States has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

COUNT 4 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE ARKANSAS MEDICAID FRAUD FALSE CLAIMS ACT, ARK. CODE ANN. §§ 20-77-901 – 20-77-911

183. This is a claim for treble damages and civil penalties under the Arkansas

Medicaid Fraud False Claims Act, Ark. Code Ann. §§ 20-77-901 – 20-77-911. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

184. Defendants violated the Arkansas Medicaid Fraud False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Arkansas as described herein.

185. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Arkansas.

186. The State of Arkansas, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Arkansas would not otherwise have paid.

187. By reason of these payments, the State of Arkansas has been damaged, and continues to be damaged, in a substantial amount.

COUNT 5 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE CALIFORNIA FALSE CLAIMS ACT, CAL. GOV'T CODE §§ 12650 – 12656

188. This is a claim for treble damages and civil penalties under the California False Claims Act, Cal. Gov't Code §§ 12650 – 12656. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

189. Defendants violated the California False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of California as described herein.

190. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of California.

191. The State of California, unaware of the false or fraudulent nature of these claims, paid such claims which the State of California would not otherwise have paid.

192. By reason of these payments, the State of California has been damaged, and continues to be damaged, in a substantial amount.

COUNT 6 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE COLORADO MEDICAID FALSE CLAIMS ACT, COL. REV. STAT. ANN. §§ 25.5-4-303.5 – 25.5-4-310

193. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5 – 25.5-4-310. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

194. Defendants violated the Colorado Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Colorado, as described herein.

195. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Colorado.

196. The State of Colorado, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Colorado would not otherwise have paid.

197. By reason of these payments, the State of Colorado has been damaged, and continues to be damaged, in a substantial amount.

COUNT 7 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE CONNECTICUT FALSE CLAIMS AND OTHER PROHIBITED ACTS UNDER STATE-ADMINISTERED HEALTH OR HUMAN SERVICES ACT ("CONNECTICUT FALSE CLAIMS ACT"), CONN. GEN. STAT. ANN. §§ 4-274 – 4-289

198. This is a claim for treble damages and civil penalties under the Connecticut False

Claims Act, Conn. Gen. Stat. Ann. §§ 4-274 – 4-289. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

199. Defendants violated the Connecticut False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Connecticut, as described herein.

200. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Connecticut.

201. The State of Connecticut, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Connecticut would not otherwise have paid.

202. By reason of these payments, the State of Connecticut has been damaged, and continues to be damaged, in a substantial amount.

COUNT 8 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT, DEL. C. ANN. TIT. 6, §§ 1201 – 1211

203. This is a claim for treble damages and civil penalties under the Delaware False Claims and Reporting Act, Del. C. Ann. tit. 6, §§ 1201 – 1211. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

204. Defendants violated the Delaware False Claims and Reporting Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Delaware, as described herein.

205. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Delaware.

206. The State of Delaware, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Delaware would not otherwise have paid.

207. By reason of these payments, the State of Delaware has been damaged, and continues to be damaged, in a substantial amount.

COUNT 9 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE DISTRICT OF COLUMBIA MEDICAID FRAUD ENFORCEMENT AND RECOVERY AMENDMENT ACT OF 2012, D.C. CODE ANN. §§ 2-381.01 – 2-381.10

208. This is a claim for treble damages and civil penalties under District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act of 2012, D.C. Code Ann. §§ 2-381.01 – 2-381.10. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

209. Defendants violated the District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act of 2012 by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the District of Columbia, as described herein.

210. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the District of Columbia.

211. The District of Columbia, unaware of the false or fraudulent nature of these claims, paid such claims which the District of Columbia would not otherwise have paid.

212. By reason of these payments, the District of Columbia has been damaged, and continues to be damaged, in a substantial amount.

COUNT 10 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE FLORIDA FALSE CLAIMS ACT, FLA. STAT. ANN. §§ 68.081 – 68.092

213. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 – 68.092. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

214. Defendants violated the Florida False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Florida as described herein.

215. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Florida.

216. The State of Florida, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Florida would not otherwise have paid.

217. By reason of these payments, the State of Florida has been damaged, and continues to be damaged, in a substantial amount.

COUNT 11 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE GEORGIA FALSE MEDICAID CLAIMS ACT, GA. CODE ANN. §§ 49-4-168 – 49-4-168.6

218. This is a claim for treble damages and civil penalties under Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 – 49-4-168.6. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

219. Defendant violated the Georgia False Medicaid Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Georgia, as described herein.

220. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Georgia.

221. The State of Georgia, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Georgia would not otherwise have paid.

222. By reason of these payments, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount.

COUNT 12 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE HAWAII FALSE CLAIMS TO THE STATE ACT, HAW. REV. STAT. §§ 661-21 – 661-31

223. This is a claim for treble damages and civil penalties under the Hawaii False Claims to the State Act, Haw. Rev. Stat. §§ 661-21 – 661-31. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

224. Defendants violated the Hawaii False Claims to the State Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Hawaii, as described herein.

225. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Hawaii.

226. The State of Hawaii, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Hawaii would not otherwise have paid.

227. By reason of these payments, the State of Hawaii has been damaged, and continues to be damaged, in a substantial amount.

COUNT 13 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE ILLINOIS FALSE CLAIMS ACT, 740 ILL. COMP. STAT. ANN. §§ 175/1 – 175/8

228. This is a claim for treble damages and civil penalties under the Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. §§ 175/1 – 175/8. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

229. Defendants violated the Illinois False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Illinois, as described herein.

230. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Illinois.

231. The State of Illinois, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Illinois would not otherwise have paid.

232. By reason of these payments, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount.

COUNT 14 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT, IND. CODE ANN. §§ 5-11-5.5-1 – 5-11-5.5-18

233. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblowers Protection Act, Ind. Code Ann. §§ 5-11-5.5-1 – 5-11-5.5-18. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

234. Defendants violated the Indiana False Claims and Whistleblowers Protection Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Indiana, as described herein.

235. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Indiana.

236. The State of Indiana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Indiana would not otherwise have paid.

237. By reason of these payments, the State of Indiana has been damaged, and continues to be damaged, in a substantial amount.

COUNT 15 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE IOWA FALSE CLAIMS ACT, IOWA CODE ANN. §§ 685.1 – 685.7

238. This is a claim for treble damages and civil penalties under the Iowa False Claims Act, Iowa Code Ann. §§ 685.1 – 685.7. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

239. Defendants violated the Iowa False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Iowa, as described herein.

240. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Iowa.

241. The State of Iowa, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Iowa would not otherwise have paid.

242. By reason of these payments, the State of Iowa has been damaged, and continues to be damaged, in a substantial amount.

COUNT 16 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW, LA. STAT. ANN. §§ 437.1 – 440.16

243. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Stat. Ann. §§ 437.1 – 440.16. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

244. Defendants violated the Louisiana Medical Assistance Programs Integrity Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Louisiana, as described herein.

245. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Louisiana.

246. The State of Louisiana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Louisiana would not otherwise have paid.

247. By reason of these payments, the State of Louisiana has been damaged, and continues to be damaged, in a substantial amount.

COUNT 17 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE MARYLAND FALSE HEALTH CLAIMS ACT, MD. CODE ANN., HEALTH-GEN. §§ 8-101 – 8-111

248. This is a claim for treble damages and civil penalties under the Maryland False Health Claims Act, Md. Code Ann., Health-General §§ 8-101 – 8-111. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

249. Defendants violated the Maryland False Health Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Maryland, as described herein.

250. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Maryland.

251. The State of Maryland, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Maryland would not otherwise have paid.

252. By reason of these payments, the State of Maryland has been damaged, and continues to be damaged, in a substantial amount.

COUNT 18 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE MASSACHUSETTS FALSE CLAIMS LAW, MASS. GEN. LAWS ANN. CH. 12, §§ 5A – 5O

253. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Law, Mass. Gen. Laws Ann. ch. 12, §§ 5A – 5O. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

254. Defendants violated the Massachusetts False Claims Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the Commonwealth of Massachusetts, as described herein.

255. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth of Massachusetts.

256. The Commonwealth of Massachusetts, unaware of the false or fraudulent nature of these claims, paid such claims which the Commonwealth of Massachusetts would not otherwise have paid.

257. By reason of these payments, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in a substantial amount.

COUNT 19 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE MICHIGAN MEDICAID FALSE CLAIM ACT, MICH. COMP. LAWS ANN. §§ 400.601 – 400.615

258. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claim Act, Mich. Comp. Laws Ann. §§ 400.601 – 400.615. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

259. Defendants violated the Michigan Medicaid False Claim Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Michigan, as described herein.

260. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Michigan.

261. The State of Michigan, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Michigan would not otherwise have paid.

262. By reason of these payments, the State of Michigan has been damaged, and continues to be damaged, in a substantial amount.

COUNT 20 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE MINNESOTA FALSE CLAIMS ACT, MINN. STAT. ANN. §§ 15C.01 – 15C.16

263. This is a claim for treble damages and civil penalties under the Minnesota False Claims Act, Minn. Stat. Ann. §§ 15C.01 – 15C.16. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

264. Defendants violated the Minnesota False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Minnesota, as described herein.

265. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Minnesota.

266. The State of Minnesota, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Minnesota would not otherwise have paid.

267. By reason of these payments, the State of Minnesota has been damaged, and continues to be damaged, in a substantial amount.

COUNT 21 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE MONTANA FALSE CLAIMS ACT, MONT. CODE ANN. §§ 17-8-401 – 17-8-416

268. This is a claim for treble damages and civil penalties under Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 – 17-8-416. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

269. Defendants violated the Montana False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Montana, as described herein.

270. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Montana.

271. The State of Montana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Montana would not otherwise have paid.

272. By reason of these payments, the State of Montana has been damaged, and continues to be damaged, in a substantial amount.

COUNT 22 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE NEVADA SUBMISSION OF FALSE CLAIMS TO STATE OR LOCAL GOVERNMENT ACT, NEV. REV. STAT. ANN. §§ 357.010 – 357.250

273. This is a claim for treble damages and civil penalties under the Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. §§ 357.010 – 357.250. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

274. Defendants violated the Nevada Submission of False Claims to State or Local Government Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Nevada, as described herein.

275. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Nevada.

276. The State of Nevada, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Nevada would not otherwise have paid.

277. By reason of these payments, the State of Nevada has been damaged, and continues to be damaged, in a substantial amount.

COUNT 23 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE NEW HAMPSHIRE MEDICAID FRAUD AND FALSE CLAIMS LAW, N.H. REV. STAT. ANN. §§ 167:61-B – 167:61-E

278. This is a claim for treble damages and civil penalties under the New Hampshire Medicaid Fraud and False Claims Law, N.H. Rev. Stat. Ann. §§ 167:61-b – 167:61-e. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

279. Defendants violated the New Hampshire Medicaid Fraud and False Claims Law

by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Hampshire, as described herein.

280. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Hampshire.

281. The State of New Hampshire, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Hampshire would not otherwise have paid.

282. By reason of these payments, the State of New Hampshire has been damaged, and continues to be damaged, in a substantial amount.

COUNT 24 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE NEW JERSEY FALSE CLAIMS ACT, N.J. STAT. ANN. §§ 2A:32C-1 – 2A:32C-18

283. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 – 2A:32C-18. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

284. Defendants violated the New Jersey False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Jersey, as described herein.

285. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Jersey.

286. The State of New Jersey, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Jersey would not otherwise have paid.

287. By reason of these payments, the State of New Jersey has been damaged, and

continues to be damaged, in a substantial amount.

**COUNT 25 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE NEW MEXICO FRAUD AGAINST TAXPAYERS ACT,
N.M. STAT. ANN. §§ 44-9-1 – 44-9-14,
AND THE NEW MEXICO MEDICAID FALSE CLAIMS ACT,
N.M. STAT. ANN. §§ 27-14-1 – 27-14-15**

288. This is a claim for treble damages and civil penalties under the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 – 44-9-14, and the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 – 27-14-15. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

289. Defendants violated the New Mexico Fraud Against Taxpayers Act and the New Mexico Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Mexico, as described herein.

290. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Mexico.

291. The State of New Mexico, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Mexico would not otherwise have paid.

292. By reason of these payments, the State of New Mexico has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 26 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE NEW YORK FALSE CLAIMS ACT,
N.Y. FIN. LAW §§ 187 – 194**

293. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. Fin. Law §§ 187 – 194. Relator realleges and incorporates the allegations in

the preceding paragraphs as if set forth fully herein.

294. Defendants violated the New York False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New York, as described herein.

295. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New York.

296. The State of New York, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New York would not otherwise have paid.

297. By reason of these payments, the State of New York has been damaged, and continues to be damaged, in a substantial amount.

COUNT 27 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE NORTH CAROLINA FALSE CLAIMS ACT, N.C. GEN. STAT. ANN. §§ 1-605 – 1-618

298. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. Ann. §§ 1-605 – 1-618. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

299. Defendants violated the North Carolina False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of North Carolina, as described herein.

300. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of North Carolina.

301. The State of North Carolina, unaware of the false or fraudulent nature of these

claims, paid such claims which the State of North Carolina would not otherwise have paid.

302. By reason of these payments, the State of North Carolina has been damaged, and continues to be damaged, in a substantial amount.

COUNT 28 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT, OKL. STAT. ANN. TIT. 63, §§ 5053 – 5054

303. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, Okl. Stat. tit. 63, §§ 5053 – 5054. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

304. Defendants violated the Oklahoma Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Oklahoma, as described herein.

305. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Oklahoma.

306. The State of Oklahoma, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Oklahoma would not otherwise have paid.

307. By reason of these payments, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount.

COUNT 29 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE RHODE ISLAND STATE FALSE CLAIMS ACT, R.I. GEN. LAWS ANN. §§ 9-1.1-1 – 9-1.1-9

308. This is a claim for treble damages and civil penalties under the Rhode Island State False Claims Act, R.I. Gen. Laws Ann. §§ 9-1.1-1 – 9-1.1-9. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

309. Defendants violated the Rhode Island State False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Rhode Island, as described herein.

310. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Rhode Island.

311. The State of Rhode Island, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Rhode Island would not otherwise have paid.

312. By reason of these payments, the State of Rhode Island has been damaged, and continues to be damaged, in a substantial amount.

COUNT 30 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE TENNESSEE FALSE CLAIMS ACT,
TENN. CODE ANN. §§ 4-18-101 – 4-18-108
AND THE TENNESSEE MEDICAID FALSE CLAIMS ACT,
TENN. CODE. ANN. §§ 71-5-181 – 71-5-185

313. This is a claim for treble damages and civil penalties under the Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 – 4-18-108, and the Tennessee Medicaid False Claims Act, Tenn. Code. Ann. §§ 71-5-181 – 71-5-185. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

314. Defendants violated the Tennessee False Claims Act and the Tennessee Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Tennessee, as described herein.

315. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Tennessee.

316. The State of Tennessee, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Tennessee would not otherwise have paid.

317. By reason of these payments, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount.

COUNT 31 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE TEXAS MEDICAID FRAUD PREVENTION LAW, TEX. HUM. RES. CODE ANN. §§ 36.001 – 36.132

318. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 – 36.132. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

319. Defendants violated the Texas Medicaid Fraud Prevention Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Texas, as described herein.

320. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Texas.

321. The State of Texas, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Texas would not otherwise have paid.

322. By reason of these payments, the State of Texas has been damaged, and continues to be damaged, in a substantial amount.

COUNT 32 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE VERMONT FALSE CLAIMS ACT, VT. STAT. ANN. TIT. 32, §§ 630 – 642

323. This is a claim for treble damages and civil penalties under the Vermont False Claims Act, Vt. Stat. Ann. tit. 32, §§ 630 – 642. Relator realleges and incorporates the

allegations in the preceding paragraphs as if set forth fully herein.

324. Defendants violated the Vermont False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State as Vermont, as described herein.

325. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Vermont.

326. The State of Vermont, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Vermont would not otherwise have paid.

327. By reason of these payments, the State of Vermont has been damaged, and continues to be damaged, in a substantial amount.

COUNT 33 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT, VA. CODE ANN. §§ 8.01-216.1 – 8.01-216.19

328. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 – 8.01-216.19. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

329. Defendants violated the Virginia Fraud Against Taxpayers Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the Commonwealth of Virginia, as described herein.

330. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Commonwealth of Virginia.

331. The Commonwealth of Virginia, unaware of the false or fraudulent nature of

these claims, paid such claims which the Commonwealth of Virginia would not otherwise have paid.

332. By reason of these payments, the Commonwealth of Virginia has been damaged, and continues to be damaged, in a substantial amount.

COUNT 34 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE WASHINGTON MEDICAID FRAUD FALSE CLAIMS ACT, WASH. REV. CODE ANN. §§ 74.66.005 – 74.66.130

333. This is a claim for treble damages and civil penalties under the Washington Medicaid Fraud False Claims Act, Wash. Rev. Code Ann. §§ 74.66.005 – 74.66.130. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

334. Defendants violated the Washington Medicaid Fraud False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Washington, as described herein.

335. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Washington.

336. The State of Washington, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Washington would not otherwise have paid.

337. By reason of these payments, the State of Washington has been damaged, and continues to be damaged, in a substantial amount.

PRAYER FOR RELIEF

WHEREFORE, Relator requests that judgment be entered against Defendants as follows:

(a) treble the Government's damages in an amount determined at trial, plus the maximum statutorily-allowed penalty for each false claim submitted in violation of the FCA or State statute set forth above;

(b) the applicable administrative civil penalties for each violation of the AKS and State-equivalent statute, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited or received, without regard to whether a portion of that amount was offered, paid or received for a lawful purpose;

(c) an award of costs and the maximum Relator award allowed pursuant to the FCA and State statutes set forth above; and

(d) such further relief as is proper.

Dated: June 19, 2017

Respectfully submitted,

/s/ Sam Baxter

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